



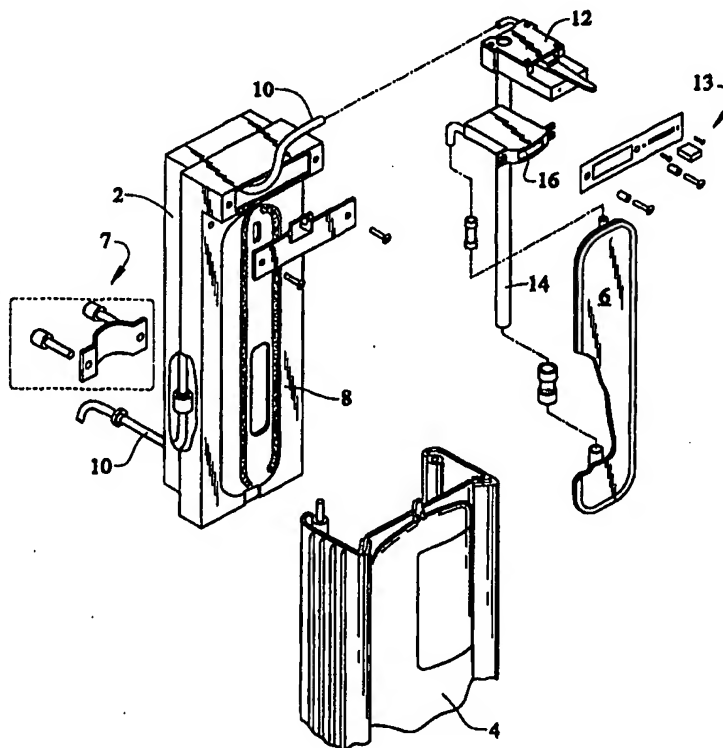
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/US98/22648</p> <p>(22) International Filing Date: 2 November 1998 (02.11.98)</p> <p>(30) Priority Data: 60/064,234 4 November 1997 (04.11.97) US</p> <p>(71) Applicant (for all designated States except US): SIMS LEVEL 1, INC. [US/US]; 160 Weymouth, Rockland, MA 02370 (US).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): OLIVER, Dana, A. [US/US]; 160 Weymouth, Rockland, MA 02370 (US). BRUNO, Joseph, A., Jr. [US/US]; 160 Weymouth, Rockland, MA 02370 (US).</p> <p>(74) Agent: CLARK, Conrad, J.; Dickinson Wright PLLC, Suite 800, 1901 L Street, N.W., Washington, DC 20036 (US).</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published With international search report.</p>

(54) Title: INFUSION SYSTEM WITH IMPROVED CONTROL VALVE

## (57) Abstract

A system and method for pressurizing bags of physiological fluids include a control valve (12) for providing deflation of a bladder (6) that compresses the bags. The toggle portion (22) of the control valve (12) is movable between a first and second position respectively for inflation and deflation of the bladder (6). When the toggle portion (22) is in the first position, the control valve (12) connects a source of pressurized air to the bladder (6), and when the toggle portion (22) is in the second position, the control valve (12) allows the bladder (6) to exhaust directly to the atmosphere through an outlet port (28) in the valve (12). The size of the outlet port is so large that it creates only very little resistance to the discharged air.



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## INFUSION SYSTEM WITH IMPROVED CONTROL VALVE

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### CROSS REFERENCE TO RELATED APPLICATION

This application claims priority of United States Provisional Application serial number 60/064,234, which was filed on November 4, 1997.

### TECHNICAL FIELD

10 This invention relates to the art of infusion pumps. In particular, the invention relates to a method and apparatus for allowing rapid deflation of a pressure infusion bladder.

### BACKGROUND

The use of infusion devices for supply of intravenous fluids to patients is well known. As well, it is known to provide these intravenous fluids under pressure to  
15 increase the flow rate. The pressure has been provided by several techniques, one of which is to engage a bag containing the fluid with an inflatable bladder. The bladder is inflated by air from a compressor, or another source of pressurized gas, which is connected to the bladder through a control valve.

It is also known to allow deflation of the bladder by a control valve that can be  
20 placed in a position whereby it vents the bladder to the atmosphere, such as is shown in US patents 3,640,276 and 4,430,078. It is also known to provide rapid deflation of a bladder by a venturi that produces a lower pressure for pumping the air out of the bladder.

A problem with prior control valves has been to combine rapid deflation, ease of  
25 operation, and low manufacturing cost.

## SUMMARY OF THE INVENTION

In accordance with the invention, a pressure infusion system includes an inflatable bladder for engaging a flexible bag of physiological fluids, a pump for supplying air under pressure, and a valve for controlling both supply of the pressurized  
5 air to the bladder and rapid exit of air from the bladder.

One feature of the invention is the use of a large-bore supply tube connecting the outlet of the control valve to the bladder. The diameter of this tube is much larger than is required to supply the bladder with air, and is made large because the control valve also allows deflation of the bladder through the tube. The increased bore size  
10 allows the bladder to deflate very rapidly without further assistance. Thus, the control valve of the invention includes an inlet for receiving air from a pressure pump, an outlet for transmitting air under pressure to the bladder, and a discharge port for allowing rapid discharge of the bladder. In the preferred embodiment, the valve comprises a  
15 body portion having a docking port and an outlet port. The body receives a toggle element that is mounted for pivotal movement between these two ports. The toggle includes an inlet port and a channel for communication with the docking port or the outlet port, depending on whether the toggle is in the inflate or deflate position.

When the toggle is in the inflate position the channel is in communication with the outlet port, and air under pressure is supplied to the bladder through the large bore  
20 tube. When the toggle is in the deflate position, the channel is in communication with the docking port, and the outlet port is open to the atmosphere. Thus, in the deflate position, the air in the bladder is rapidly discharged to the atmosphere to allow a full bag of fluids to be installed easily.

The invention also includes a method of inflating and deflating an expandable  
25 bladder in conjunction with pressurizing a flexible bag of physiological fluid by inflating the expandable bladder by introducing pressurized fluid into the expandable bag first through an inlet channel having a first cross sectional area and then through a supply tube in communication with the expandable bladder. The bladder can then be deflated by bypassing the inlet channel to release the pressurized fluid first through the supply  
30 tube and then through an outlet exposed by the bypassing of the inlet channel, the

outlet having a second cross sectional area greater than the first cross sectional area of the inlet channel.

It will be appreciated that the valve of the invention is unique in that the inlet port is quite small relative to the outlet port. Similarly, the tubing connecting the air pump to the inlet is much smaller than the supply tube connecting the valve to the bladder.

The system of the invention is preferably implemented by mounting the control valve on the base of the device such that the toggle is easily accessed by an operator. This position is such that the operator can easily move the toggle between inflate and discharge positions while opening or closing the door to the device and exchanging the fluid bags.

### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective of an infusion system in accordance with the invention.

Figure 2 is an exploded perspective of a control valve in accordance with the invention.

Figures 3a through 3d is a series of views detailing the toggle portion of the valve of figure 2.

### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

With reference to figure 1, a system in accordance with the invention includes a housing 2 to which a door 4 is pivotally mounted, the housing secured by fastening components 7. A pressure bladder 6 is secured to a depression in a front wall 8 of the housing for engaging a bag of physiological fluids (not shown) held between the bladder and the door. The physiological fluids are connected to a patient as known in the art for infusion. When the bladder is inflated, the volume between the rear wall and the bag decreases, thus applying pressure to the fluids in the bag to infuse the fluids under pressure.

The bladder is inflated by air supplied from a pump (not shown) through an inlet tube 10. The inlet tube is connected to the inlet of a control valve 12, which will be described further below. The outlet of the control valve is connected to a supply tube

14, which is in turn connected to the bladder. A pressure monitor gauge 16 is also connected to the bladder to allow the operator to monitor the bladder pressure. The control valve 12 is secured by fastening assembly components 13.

5 With reference to figure 2, the control valve includes a body portion 18 and a cover 20, which form a cavity for receiving a toggle portion 22. As will be described in connection with figure 3 the toggle provides an inlet and a connecting channel. The body provides a docking position 24, which is preferably a dead end depression containing an O-ring 26 for sealing the toggle to the floor of the body when the toggle is in the docking position. The body also includes an outlet port 28 and a second O-ring  
10 30 for sealing the toggle to the outlet port when in that position.

With reference to figures 3a-3d, the toggle includes an inlet 32, which is part of a channel 34. The inlet tube 10 from the pump or other source of pressurized air is attached to the inlet 32 as shown in figure 1. The channel 34 communicates the fluid under pressure to the dead end docking port 24 when the toggle is in one position and  
15 to the outlet port 28 when the toggle is in a second position. The toggle 22 pivots about pin 29, see Figure 1, the pin engaging bore 31 as shown in Figure 3b.

Referring again to figure 2, the cover 20 includes an opening 36 aligned with the outlet port 28, and there is a substantial open space above the outlet port 28 between the cover and the floor of the body portion when the toggle is not covering the outlet  
20 port.

Thus, the operation of the system is as follows. When the bladder is to be inflated, the operator moves the toggle to the position wherein it covers the outlet port 28. Air from the source of pressurized air flows through the channel 34, through the supply tube 14 and into the bladder. When the operator wishes to change bags of fluid,  
25 the toggle is moved to the position where it covers the docking port, which accomplishes two things.

First, moving the toggle to the docking position directs the air from the pump to the dead end, which will automatically shut off the pump as the pressure increases. Secondly, and more importantly, the supply tube will be open to the atmosphere,  
30 whereby the bladder will discharge quickly.

In the preferred embodiment, the dimensions of the supply tube are such that there is only negligible pressure drop between the bladder and the atmosphere when in the discharge mode. In other words, the bladder achieves pressure equilibrium with the atmosphere almost instantaneously, thus obviating the necessity of assistance in the  
5 discharge. In the preferred embodiment the inside diameter of the supply tube is at least 0.375 inch to provide adequate venting from a normal bladder used of blood bags. The outside diameter may be 0.50 inch or larger. The inside diameter of the inlet tube  
10 is preferably about 0.125 inch with an outside diameter of about 0.250 inch.

Modifications within the scope of the appended claims will be apparent to those  
10 of skill in the art.

I claim:

1. A control valve for controlling inflation and deflation of a bladder comprising:
    - a body having a port for fluid communication with a bladder,
    - a toggle mounted to said body for movement between first and second positions
    - 5 and having an inlet for receiving pressurized fluid and a channel communicating with said inlet for conducting said pressurized fluid,

wherein said port is located in said body to be in fluid communication with said channel when said toggle is said first of said positions and in free communication with the atmosphere when said toggle is in said second of said positions, and wherein said

  - 10 outlet port is larger than said inlet and provides a negligible pressure drop to said fluid when said toggle is in said second of said positions.
2. A control valve according to claim 1 wherein said toggle is mounted to said body for pivotal movement.
  3. A control valve according to claim 2 wherein said body has a cavity for receiving
  - 15 said toggle.
  4. A control valve according to claim 1 wherein the cross sectional area of said outlet port is at least about 0.1 in<sup>2</sup>.
  5. A combination comprising a control valve according to claim 1, a bladder, a supply tube connecting said port to said bladder, and an inlet tube for connecting a source of
  - 20 pressurized air to said inlet, and wherein said supply tube is at least as large as said port.
  6. A combination according to claim 5 further comprising a housing for containing said valve and said bladder and wherein said toggle has an operating lever extending outward of said housing.
  - 25 7. A combination according to claim 6 further comprising means for supporting a flexible bag of physiological fluids.
  8. A control valve according to claim 1 wherein said port is uncovered when said toggle is in said second of said positions.



9. A valve for controlling inflation and deflation of a bladder comprising:

means forming an outlet port for fluid communication with a bladder, the size of said port being large enough to create no more than a negligible resistance to the flow of a fluid from said bladder, and

5 means for selectively communicating a fluid under pressure to said outlet port.

10. A valve according to claim 9 wherein said means forming an outlet port further includes means for mounting said means for selectively communicating a fluid under pressure for pivotal movement between a first position wherein said fluid under pressure is in communication with said outlet port and a second position wherein said  
10 outlet port is exposed to the atmosphere.

11. A valve according to claim 9 wherein said means for selectively communicating said fluid under pressure comprises a channel for carrying said fluid under pressure and an inlet to said channel, and said outlet port is larger than said channel and said inlet.

12. A valve according to claim 9 in combination with a bladder, means for housing  
15 said bladder and said valve, and means for supporting a flexible bag of physiological fluids in contact with said bladder.

13. In an apparatus for pressurizing a flexible bag of physiological fluids having an expandable bladder, means for supporting said bag of physiological fluids in contact with said bladder, and a source of pressurized fluid, the improvement comprising a  
20 control valve connected to said source of pressurized fluid through an inlet of a first cross sectional area and connected to said bladder through an outlet of a second cross sectional area, and means for connecting said inlet to said outlet to inflate said bladder and for exposing said outlet to the atmosphere to deflate said bladder, and wherein said second cross sectional area creates no more than a negligible pressure drop during  
25 deflation.

14. An apparatus according to claim 13 wherein said control valve comprises a body having said outlet and a toggle having said inlet, and said toggle is mounted to said body for movement between a first position where said inlet is in fluid communication

with said outlet and a second position wherein said outlet is exposed to the atmosphere.

15. An apparatus according to claim 14 wherein said control valve is pivotally connected to said body.

5 16. A method of inflating and deflating an expandable bladder in conjunction with pressurizing a flexible bag of physiological fluid comprising:

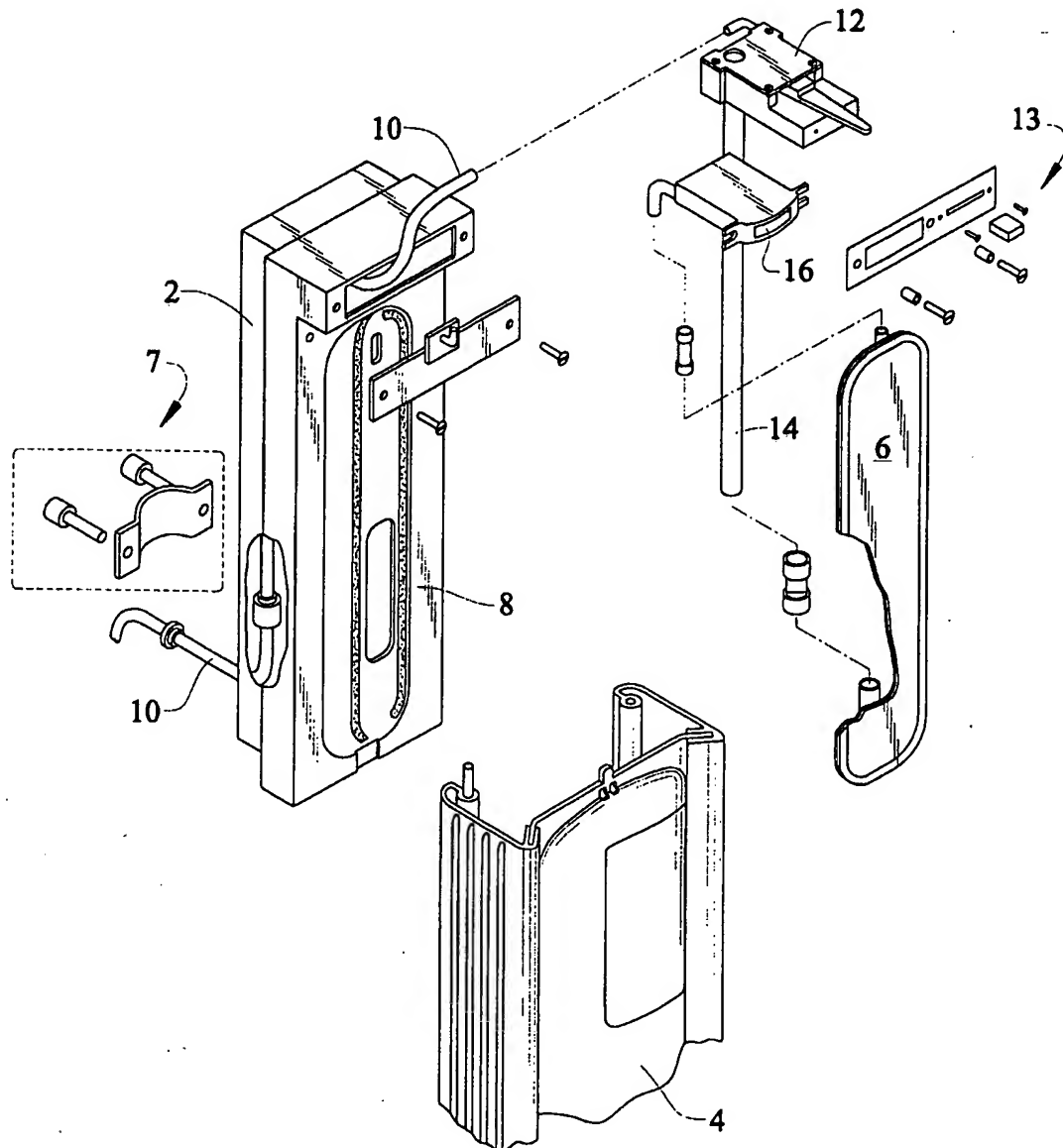
a) inflating the expandable bladder by introducing pressurized fluid into the expandable bag first through an inlet channel having a first cross sectional area and then through a supply tube in communication with the expandable bladder; and

10 b) deflating the expandable bladder by bypassing the inlet channel to release the pressurized fluid first through the supply tube and then through an outlet exposed by the bypassing of the inlet channel, the outlet having a second cross sectional area greater than the first cross sectional area of the inlet channel.

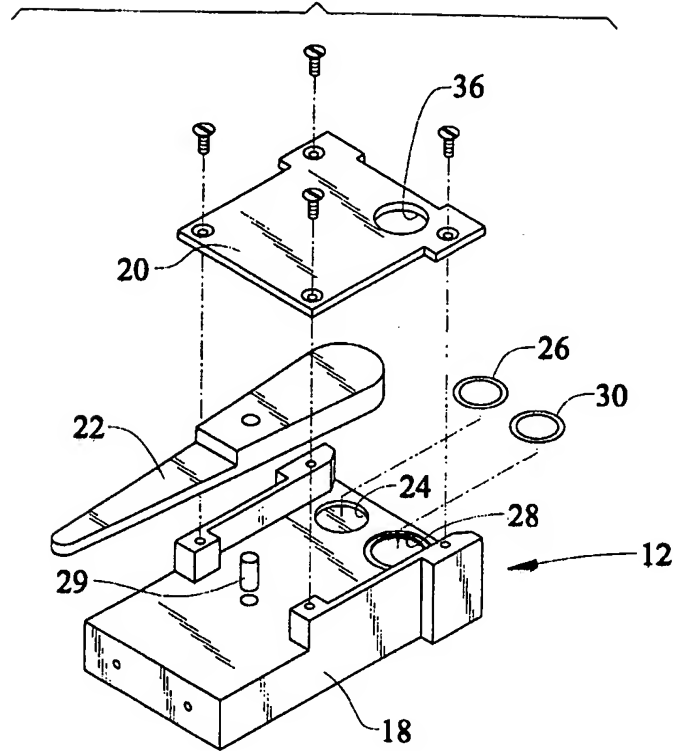
15 17. The method of claim 16, wherein the inlet channel is formed in a control valve member and the control valve member is moved from a first position for the inflating step to a second position for the bypassing step.

18. The method of claim 16, wherein the inlet channel is moved with respect to the outlet.

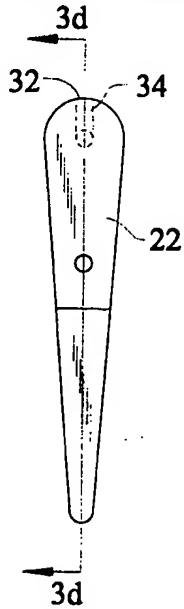
20 19. The method of claim 16, wherein the second cross sectional area is such that deflation occurs with a minimum of pressure drop.

*FIG. 1*

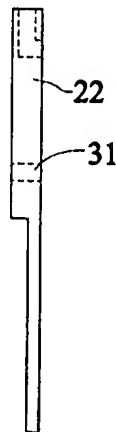
*FIG. 2*



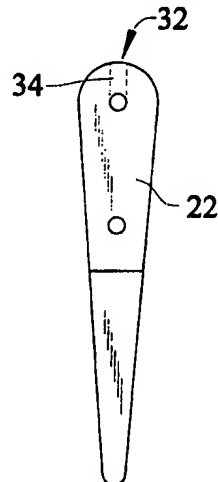
*FIG. 3a*



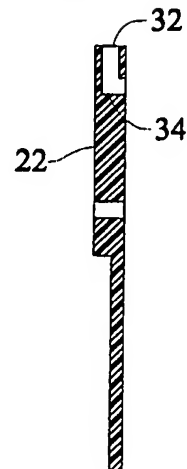
*FIG. 3b*



*FIG. 3c*

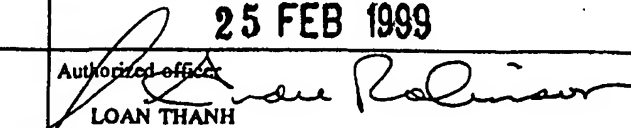


*FIG. 3d*



# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US98/22648

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(6) : A61M 5/00 US CL : 604/246 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) U.S. : 137/625.25; 604/30, 31, 33, 45, 118, 131, 132, 133, 140-142, 151, 153, 246, 248, 249, 256 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P ----- Y,P	US 5,720,728 A (FORD) 24 February 1998, Figs. 1-5B, col. 1 line 19 to col. 2 line 35, and cols. 4-8.	1-3, 7-17, 19 ----- 4, 5
A,P	US 5,743,878 A (ROSS et al.) 28 April 1998, Figs. 1-3 and 7-8, and entire document.	1-19
A	US 5,484,415 A (KRIESEL) 16 January 1996, entire document.	1-19
X --- Y	US 5,318,515 A (WILK) 07 June 1994, Figs. 1-3.	1-3, 9-11 ----- 4, 12
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "B" earlier document published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "A" document member of the same patent family	
Date of the actual completion of the international search  26 JANUARY 1999	Date of mailing of the international search report  25 FEB 1999	
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# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US98/22648

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3,469,578 A (BIERMAN) 30 September 1969, entire document.	1-19